

### **REMARKS**

This Amendment is being submitted in response to the Office Action mailed on June 7, 2007 in connection with the above-identified application.

Reconsideration of the above-identified application in view of the foregoing amendments and following remarks is respectfully requested.

#### ***Status of the Application***

Claims 1-8 are currently pending and under consideration. Claims 1, 7 and 8 have been amended as will be discussed in more detail below. No new matter has been added as a result of these amendments. Moreover, these amendments are clearly supported by the specification as originally filed.

#### ***Rejection of Claims 1-3 and 7 in view of 35 U.S.C. Sections 102(a) and 102(e)***

Claims 1-3, and 7 are rejected under 35 U.S.C. Sections 102(a) and 102(e) as being anticipated by WO 02/45692 (hereinafter "WO '692"). Applicant traverses this rejection.

More particularly, the Examiner has maintained this rejection suggesting that WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension, to be administered to a patient in need thereof. The Examiner also states that this reference teaches adding inorganic basic salts, and that among the proton pump inhibitors listed is lansoprazole (The Examiner refers to pages 6, and page 1 and example 6, page 13, respectively). The Examiner further argues that this reference teaches that the dosage form is in the form of powder and that prior to administration the active agent is combined with the liquid vehicle (The Examiner refers to page 3). The Examiner points to Example C as disclosing the composition suspended in purified water. According to the Examiner, water is a liquid vehicle with a pH greater than 6.5. Therefore, it is the Examiner's opinion that since a suspension is formed in Example C that the composition has a sufficient viscosity to form a suspension.

The Examiner acknowledges Applicant's prior remarks made in the previous Amendment, but suggests that since the Applicant has used the terminology "comprising", any number of components regardless of their material effect on the composition can be included in the claimed composition. While not agreeing with this rejection, in order to expedite prosecution, Applicant has amended the claims to recite that the composition is in "liquid form". In view of this amendment to the claims, Applicant submits that WO '692 does not disclose or suggest Applicant's claimed invention. Applicant further believes that it is improper of the Examiner to suggest that additional components could be included in the claimed composition that would change the pharmacokinetic effect or benefits achieved by the claimed invention. In particular, it is improper to include other ingredients or components whose material effect would clearly result in the claimed composition not being in a liquid form.

Applicant submits that WO '692 comprises an aqueous base, an excipient, a thickener and a matrix composed of at least one paraffin wax (See WO '692, page 3, first full paragraph). As previously argued by Applicant, these compositions are very different from the compositions claimed by Applicant, in particular, compositions in liquid form. Paraffins are practically insoluble in water and are stored at temperatures of not more than 40°C. Functionally, paraffins are used as a base for ointments and as stiffening agents. Paraffins are included in the FDA's Inactive Ingredients Guide and are used in oral capsules and tablets and topical emulsions and ointments. Clearly, paraffins would not be included in compositions in liquid form, as recited by the claimed invention. Moreover, the inclusions of paraffins would in essence teach away from the claimed invention.

Thereupon, because WO '692 fails to disclose each and every element of the claimed invention, the rejection of claims 1-3 and 7 under 35 U.S.C. Sections 102(a) and 102(e) is improper and should be withdrawn. .

***Rejection of Claims 1-3, 7 and 8 in view of 35 U.S.C. Section 102(b)***

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. Section 102(b) as being anticipated by WO 94/25070 (hereinafter "WO '070"). Applicant respectfully traverses this rejection.

According to the Examiner, WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (The Examiner refers to claim 6). The Examiner further suggests that water is a liquid vehicle that has a pH greater than 6.5. According to the Examiner, suitable pH buffers are used to improve the functional stability of the composition (The Examiner refers to page 8). The Examiner further suggests that the proton pump inhibitor is lansoprazole (The Examiner refers to claim 11), and that WO '070 teaches making a kit comprising the dry enteric-coated beads (The Examiner refers to claims 14 and 15), and that the enterically coated beads are added to a liquid vehicle, such as water.

The Examiner acknowledged Applicant's remarks in its previous Amendment, but did not consider them to be persuasive since the claims did not require the composition to be in liquid form. As previously argued by Applicant, WO '070 discloses a paste-like gel composition comprising proton pump inhibitors (See, WO '070, page 3). While not agreeing with the rejection, Applicant has amended the pending claims to recite that the composition is in liquid form. By definition, paste-like gel compositions are different from liquid compositions, such that paste-like compositions are generally used for topical applications and are semi-solid dosage forms.

Accordingly, in view of the amendments to the claims, it is clear that WO '070 fails to disclose each and every element of the claimed invention. Thereupon, the rejection of claims 1-3, 7 and 8 under 35 U.S.C. Section 102(b) should be withdrawn.

***Rejection of Claims 1-8 in view of 35 U.S.C Section 103(a)***

Claims 1-8 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over WO 02/45692. Applicant respectfully traverses this rejection.

The Examiner continues to maintain many of the same arguments made in connection with the 35 U.S.C. Sections 102(a) and 102(e) rejections. Moreover, the Examiner failed to address Applicant's remarks contained in its previous Amendment suggesting that the Examiner

failed to establish a *prima facie* case of obviousness. In particular, the Examiner simply suggests that “it would have been obvious to one of ordinary skill in the art to adjust the thickening ingredients in the composition to achieve the desired viscosity”. Applicant continues to maintain that this statement is nothing more than conjecture, especially since it has not been further supported by any comments or support cited by the Examiner. The Examiner has failed to cite any support that would provide a reasonable probability of success that one skilled in the art would obtain Applicant’s invention having the viscosity requirements as recited by the claims. As admitted by the Examiner, WO ‘692 does not teach the specific viscosity requirement.

Moreover, in view of Applicant’s amendments to the pending claims, as well as the remarks provided above, it would not have been obvious to achieve the viscosity of the claimed invention using paraffin as required by WO ‘692. The claims as currently pending require a composition in liquid form. Accordingly, it would not have been obvious to use paraffin, a insoluble agent, to achieve the required viscosity of the claimed composition.

The Examiner further suggests that although the reference does not specifically disclose a kit composition, it does disclose first making the microgranules and then adding them to a liquid vehicle. Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art that the two components – the microgranules and the liquid vehicle – would need to be in separate containers prior to being mixed. Once again, the Examiner has failed to meet her burden of establishing a *prima facie* case of obviousness. There is absolutely no suggestion, motivation or teaching in WO ‘692 regarding kits nor the placement of the microgranules and the liquid in separate containers prior to mixing. Moreover, even assuming *arguendo* that WO ‘692 included the use of a kit, the kit would not include the formation of a composition in liquid form, as recited by the claimed invention.

Accordingly, in view of the arguments made above, Applicant submits that the rejection of claims 1-8 as being unpatentable as being obvious in view of WO ‘692 is improper and should be withdrawn.

Lastly, the Examiner has also rejected claims 1-8 under 35 U.S.C. Section 103(a) as being unpatentable over WO 94/25070 (hereinafter “WO ‘070”). Once again, in discussing WO ‘070, the Examiner repeats many of the same arguments made above in connection with the 35

U.S.C. Section 102(b) rejection. The Examiner acknowledges that “[T]he reference [WO ‘070] does not teach the viscosity requirement”. Applicant submits that the Examiner fails to make a *prima facie* case of obviousness, or even address Applicant’s comments in its last Amendment suggesting the same. Instead, the Examiner simply makes the conclusory statement that “[O]ne of ordinary skill in the art would be motivated to make a solution with a viscosity that is suitable to form a suspension. One of ordinary skill in the art would know how to add thickening agents and other ingredients to achieve the desired viscosity.” Applicant respectfully traverses this rejection.

The amended claims provide for a composition in liquid form. In contrast, WO ‘070 provides for a paste-like composition. In view of the remarks previously recited in connection with WO ‘070, Applicant submits that it would not have been obvious to one of ordinary skill in the art to achieve the viscosity recited by Applicant’s claimed invention based on the paste-like composition recited in WO ‘070. The Examiner’s statement that one skilled in the art would be “motivated” to make a solution with a viscosity that is “suitable” to form a suspension is nothing more than conjecture. Moreover, there is also no disclosure or suggestion in WO ‘070 of a kit to form a composition in a liquid form. One again, WO ‘070 recites a paste-like composition.

In view of the arguments made above, Applicant submits that the rejection of claim 1-8 as being unpatentable as being obvious in view of WO ‘070 is improper and should be withdrawn.

**CONCLUSION**

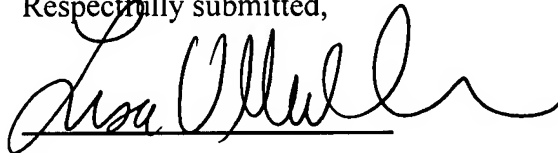
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 04-2223.

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